Eric I. Abraham (eabraham@hillwallack.com)
William P. Murtha (wmurtha@hillwallack.com)
Kristine L. Butler (kbutler@hillwallack.com)
HILL WALLACK LLP
21 Roszel Road
Princeton, NJ 08540
T: (609) 924-0808
F: (609) 452-1888

Mark H. Remus (mremus@crowell.com)
Laura A. Lydigsen (llydigsen@crowell.com)
Mary E. LaFleur (mlafleur@crowell.com)
Eric Moss (emoss@crowell.com)
CROWELL & MORING LLP
455 North Cityfront Plaza Drive
NBC Tower, Suite 3600
Chicago, IL 60611
T: (312) 321-4200
F: (312) 321-4299

Attorneys for Defendant Sandoz Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ESPERION THERAPEUTICS, INC., Plaintiff, v. SANDOZ INC., Defendant.	Civil Action No.: 2:24-cv-06387

DEFENDANT SANDOZ INC.'S ANSWER, DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT

Defendant Sandoz Inc. ("Sandoz") hereby files its Answer, Defenses, and Counterclaims in response to the Complaint for Patent Infringement ("Complaint") filed on May 23, 2024, by Plaintiff Esperion Therapeutics, Inc. ("Plaintiff").

ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT

1. This is an action for patent infringement by Esperion Therapeutics, Inc. ("Esperion") under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendant Sandoz Inc. ("Sandoz"). This action arises out of Sandoz's submission of Abbreviated New Drug Application ("ANDA") Nos. 219347 and 219346 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of NEXLETOL® and NEXLIZET® prior to the expiration of U.S. Patent Nos. 11,926,584, 11,760,714, 11,613,511, 10,912,751, and 11,744,816.

ANSWER:

Paragraph 1 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Plaintiff's Complaint purports to state an action for infringement of U.S. Patent Nos. 11,926,584 ("'584 patent"), 11,760,714 ("'714 patent"), 11,613,511 ("'511 patent"), 10,912,751 ("'751 patent"), and 11,744,816 ("'816 patent") (collectively, "Patents-in-Suit") and that this action purports to arise under the patent laws of the United States, 35 U.S.C. § 100 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. Sandoz further admits that the action purports to relate to Sandoz's submission of Abbreviated New Drug Application ("ANDA") Nos. 219347 ("Sandoz's Mono ANDA") and 219346 ("Sandoz's Combo ANDA") (collectively, "Sandoz's ANDAs") to the U.S. Food and Drug Administration ("FDA") to respectively seek approval of bempedoic acid tablets, 180 mg ("Sandoz's Mono ANDA Product") and bempedoic acid and ezetimibe tablets, 180 mg / 10 mg ("Sandoz's Combo ANDA Product") (collectively, "Sandoz's ANDA Products"). Sandoz further admits that it submitted Sandoz's ANDAs to the FDA seeking approval to market Sandoz's ANDA Products in the United States before the expiration of the Patents-in-Suit. Sandoz denies the remaining allegations of Paragraph 1.

PARTIES

2. Plaintiff Esperion is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108.

ANSWER:

Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 2 and on that basis denies these allegations.

3. Upon information and belief, Defendant Sandoz is a corporation organized and existing under the laws of Delaware, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

ANSWER:

Sandoz admits that it is a corporation organized and existing under the laws of Delaware and maintains a place of business at 100 College Road West, Princeton, New Jersey 08540-6604. Sandoz denies the remaining allegations of Paragraph 3.

4. Upon information and belief, Sandoz is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

ANSWER:

Sandoz admits that it markets pharmaceutical products, which include generic drug products that are the subject of ANDAs approved by the FDA. Sandoz denies the remaining allegations of Paragraph 4.

5. Upon information and belief, Sandoz directly or through its affiliates markets and sells drug products throughout the United States, including in the state of New Jersey.

ANSWER:

Sandoz admits that it markets pharmaceutical products in the United States, including in the state of New Jersey. Sandoz denies the remaining allegations of Paragraph 5.

6. Upon information and belief, Sandoz directly or through its affiliates markets and sells drug products throughout the United States, including in New Jersey.

ANSWER:

Sandoz admits that it markets pharmaceutical products in the United States, including in New Jersey. Sandoz denies the remaining allegations of Paragraph 6.

7. Upon information and belief, Sandoz works directly or through its affiliates on the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products for the United States market, including New Jersey.

ANSWER:

Sandoz admits that it markets pharmaceutical products in the United States, including in New Jersey. Sandoz denies the remaining allegations of Paragraph 7.

8. Upon information and belief, Sandoz prepared and submitted ANDA No. 219347 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLETOL® (the "Sandoz NEXLETOL® ANDA Product") prior to the expiration of U.S. Patent Nos. 11,926,584, 11,760,714 and 11,613,511.

ANSWER:

Sandoz admits that it submitted Sandoz's Mono ANDA to FDA seeking approval to market Sandoz's Mono ANDA Product prior to the expiration of the '584, '714, and '511 patents. Sandoz denies the remaining allegations of Paragraph 8.

9. Upon information and belief, Sandoz directly or through its affiliates developed the Sandoz NEXLETOL® ANDA Product.

ANSWER:

Sandoz admits that it submitted Sandoz's Mono ANDA to FDA seeking approval to market Sandoz's Mono ANDA Product. Sandoz denies the remaining allegations of Paragraph 9.

10. Upon information and belief, Sandoz is seeking regulatory approval from the FDA to market and sell the Sandoz NEXLETOL® ANDA Product throughout the United States, including in New Jersey.

ANSWER:

Sandoz admits that it submitted Sandoz's Mono ANDA to FDA seeking approval to

market Sandoz's Mono ANDA Product in the United States. Sandoz denies the remaining allegations of Paragraph 10.

11. Upon information and belief, Sandoz intends to obtain approval for Sandoz's ANDA No. 219347, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Sandoz NEXLETOL® ANDA Product in the United States, including in New Jersey.

ANSWER:

Sandoz admits that it submitted Sandoz's Mono ANDA to FDA seeking approval to market Sandoz's Mono ANDA Product in the United States. Sandoz denies the remaining allegations of Paragraph 11.

12. Upon information and belief, Sandoz prepared and submitted ANDA No. 219346 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLIZET® ("Sandoz NEXLIZET® ANDA Product") prior to the expiration of U.S. Patent Nos. 11,926,584, 11,760,714, 11,613,511, 10,912,751, and 11,744,816.

ANSWER:

Sandoz admits that it submitted Sandoz's Combo ANDA to FDA seeking approval to market Sandoz's Combo ANDA Product prior to the expiration of the '584, '714, '511, '751, and '816 patents. Sandoz denies the remaining allegations of Paragraph 12.

13. Upon information and belief, Sandoz directly or through its affiliates developed the Sandoz NEXLIZET® ANDA Product.

ANSWER:

Sandoz admits that it submitted Sandoz's Combo ANDA to FDA seeking approval to market Sandoz's Combo ANDA Product. Sandoz denies the remaining allegations of Paragraph 13.

14. Upon information and belief, Sandoz is seeking regulatory approval from the FDA to market and sell the Sandoz NEXLIZET® ANDA Product throughout the United States, including in New Jersey.

ANSWER:

Sandoz admits that it submitted Sandoz's Combo ANDA to FDA seeking approval to market Sandoz's Combo ANDA Product in the United States. Sandoz denies the remaining allegations of Paragraph 14.

15. Upon information and belief, Sandoz intends to obtain approval for Sandoz's ANDA No. 219346, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Sandoz NEXLIZET® ANDA Product in the United States, including in New Jersey.

ANSWER:

Sandoz admits that it submitted Sandoz's Combo ANDA to FDA seeking approval to market Sandoz's Combo ANDA Product in the United States. Sandoz denies the remaining allegations of Paragraph 15.

JURISDICTION AND VENUE

16. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER:

Paragraph 16 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that this action purports to arise under the patent laws of the United States, 35 U.S.C. § 100 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. Sandoz further does not contest this Court's subject matter jurisdiction solely for the limited purposes of this action only, and expressly reserves the right to contest subject matter jurisdiction in any other case as to any party, including Plaintiff. Sandoz denies the remaining allegations of Paragraph 16.

17. This Court has personal jurisdiction over Sandoz because, on information and belief, Sandoz is a corporation with its principal place of business in New Jersey and is qualified to do business in New Jersey.

ANSWER:

Paragraph 17 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it maintains a place of business in Princeton, New Jersey. In addition, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. Sandoz denies the remaining allegations of Paragraph 17.

18. In view of the foregoing, Sandoz is subject to general personal jurisdiction in New Jersey.

ANSWER:

Paragraph 18 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. Sandoz denies the remaining allegations of Paragraph 18.

19. This Court also has personal jurisdiction over Sandoz because Sandoz, among other things, has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of its ANDA No. 219347 in New Jersey, and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219347, Sandoz will make, use, import, sell, and/or offer for sale the Sandoz NEXLETOL® ANDA Product in the United States, including in New Jersey, prior to the expiration of U.S. Patent Nos. 11,926,584, 11,760,714 and 11,613,511.

ANSWER:

Paragraph 19 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted Sandoz's Mono ANDA to FDA seeking approval to market Sandoz's Mono ANDA Product in the United States prior to the expiration of the '584, '714, and '511 patents. In addition, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. Sandoz denies the remaining allegations of Paragraph 19.

20. This Court has personal jurisdiction over Sandoz because Sandoz, among other things, has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of its ANDA No. 219346 in New Jersey, and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219346, Sandoz directly or through its affiliates, will make, use, import, sell, and/or offer for sale the Sandoz NEXLIZET® ANDA Product in the United States, including in New Jersey, prior to the expiration of U.S. Patent Nos. 11,926,584, 11,760,714, 11,613,511, 10,912,751, and 11,744,816.

ANSWER:

Paragraph 20 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted Sandoz's Combo ANDA to FDA seeking approval to market Sandoz's Combo ANDA Product in the United States prior to the expiration of the '584, '714, '511, '751, and '816 patents. In addition, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. Sandoz denies the remaining allegations of Paragraph 20.

21. This Court also has personal jurisdiction over Sandoz because, among other things, this action arises from Sandoz's actions directed toward New Jersey, and because, upon information and belief, Sandoz has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey, including by,

among other things, (1) intentionally marketing and providing its generic pharmaceutical products to residents of New Jersey; (2) enjoying substantial income from New Jersey; and (3) creating a presence in New Jersey through its registration with both the New Jersey Division of Revenue and Enterprise Services, as a business operating in New Jersey under Business Entity ID Nos. 0101056767 and 0100097265, and the New Jersey Department of Health, as a drug manufacturer and wholesaler, and maintaining a Drug and Medical Device Certificate of Registration under Registration No. 5003732. Sandoz has, therefore, purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here.

ANSWER:

Paragraph 21 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it maintains a place of business in Princeton, New Jersey. In addition, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. Sandoz denies the remaining allegations of Paragraph 21.

22. In addition, this Court has personal jurisdiction over Sandoz because, among other things, upon information and belief, (1) Sandoz filed its ANDAs for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of the Sandoz NEXLETOL® ANDA Product and the Sandoz NEXLIZET® ANDA Product in the United States, including in New Jersey, and (2) upon approval of Sandoz's ANDAs, Sandoz will market, distribute, offer for sale, sell, and/or import the Sandoz NEXLETOL® ANDA Product and the Sandoz NEXLIZET® ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of these Sandoz ANDA Products in New Jersey. Upon information and belief, upon approval of Sandoz's ANDAs, the Sandoz NEXLETOL® ANDA Product and the Sandoz NEXLIZET® ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have substantial effects on New Jersey and lead to foreseeable harm and injury to Esperion.

ANSWER:

Paragraph 22 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted Sandoz's ANDAs to FDA seeking approval to market Sandoz's ANDA Products in the United States. In addition, Sandoz does not contest

this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. Sandoz denies the remaining allegations of Paragraph 22.

23. This Court also has personal jurisdiction over Sandoz because Sandoz regularly engages in patent litigation in this forum, and affirmatively avails itself of the jurisdiction of this Court by filing Complaints and counterclaims in this District and by being sued in this District without challenging personal jurisdiction, including in at least *Axsome Malta Ltd. v. Alkem Laboratories, Ltd.*, C.A. No. 24-cv-04608, Dkt. No. 14 (D.N.J. filed Apr. 26, 2024); *Allergan Sales, LLC v. Sandoz, Inc.*, C.A. No. 17-cv-10129, Dkt. No. 18 (D.N.J. filed Dec. 19, 2017); *Boehringer Ingelheim Pharms., Inc. v. Sandoz, Inc.*, C.A. No. 17-cv-08825, Dkt. No. 14 (D.N.J. filed Jan. 23, 2018); and *Sandoz Inc. v. Daiichi Sankyo, Inc.*, C.A. No. 16-cv-00994, Dkt. 1, (D.N.J. filed Feb. 22, 2016).

ANSWER:

Paragraph 23 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it was a party before this Court in the civil actions listed in Paragraph 23, and states that the filings in those cases speak for themselves. In addition, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. Sandoz denies the remaining allegations of Paragraph 23.

24. Based on the foregoing systematic and continuous contacts with New Jersey, Sandoz is subject to specific personal jurisdiction in New Jersey.

ANSWER:

Paragraph 24 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. Sandoz denies the remaining allegations of Paragraph 24.

25. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for Sandoz to litigate this action in this Court, and Sandoz is subject to personal jurisdiction in New Jersey.

ANSWER:

Paragraph 25 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. Sandoz denies the remaining allegations of Paragraph 25.

26. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b). *In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018).

ANSWER:

Paragraph 26 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest venue in this judicial district solely for the limited purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party, including Plaintiff. Sandoz denies the remaining allegations of Paragraph 26.

27. Venue is proper in this Court under 28 U.S.C. § 1400(b) because Sandoz is a corporation with its regular and established principal place of business in New Jersey, is subject to personal jurisdiction in this Court, as set forth above, has committed acts of infringement, and, upon information and belief, will commit further acts of infringement in New Jersey.

ANSWER:

Paragraph 27 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it maintains a place of business in Princeton, New Jersey. In addition, Sandoz does not contest venue in this judicial district solely for the limited purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party, including Plaintiff. Sandoz denies the remaining allegations of Paragraph 27.

28. Venue is also proper in this Court for Sandoz because it has a regular and established place of business in New Jersey at least because, upon information and belief, it (1) has engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities; and (2) has acted to prepare and file its ANDAs, and to seek approval from the FDA to market and sell the Sandoz NEXLETOL® ANDA Product and Sandoz NEXLIZET® ANDA Product in the United States, including in New Jersey.

ANSWER:

Paragraph 28 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it maintains a place of business in Princeton, New Jersey. Sandoz further admits that it submitted Sandoz's ANDAs to FDA seeking approval to market Sandoz's ANDA Products in the United States. In addition, Sandoz does not contest venue in this judicial district solely for the limited purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party, including Plaintiff. Sandoz denies the remaining allegations of Paragraph 28.

THE PATENTS-IN-SUIT

29. U.S. Patent No. 11,926,584 (the "'584 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on March 12, 2024. A true and correct copy of the '584 Patent is attached hereto as "Exhibit A."

ANSWER:

Paragraph 29 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Exhibit A of Plaintiff's Complaint purports to be a copy of the '584 patent. Sandoz further admits that the face of the '584 patent states that the '584 patent purports to have been issued on March 12, 2024. Sandoz further admits that, on its face, the '584 patent is titled "Methods of Making Bempedoic Acid and Compositions of the Same." Sandoz denies the remaining allegations of Paragraph 29.

30. Esperion is the assignee of, and holds all rights, title and interest in the '584 Patent.

ANSWER:

Paragraph 30 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the online records of the U.S. Patent and Trademark Office ("USPTO") list Plaintiff as the assignee of the '584 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 30 and on that basis denies these allegations.

31. The '584 Patent currently expires on June 19, 2040.

ANSWER:

Paragraph 31 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists June 19, 2040 as the expiration date of the '584 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 31 and on that basis denies these allegations.

32. U.S. Patent No. 11,760,714 (the "'714 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on September 19, 2023. A true and correct copy of the '714 Patent is attached hereto as "Exhibit B."

ANSWER:

Paragraph 32 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Exhibit B of Plaintiff's Complaint purports to be a copy of the '714 patent. Sandoz further admits that the face of the '714 patent states that the '714 patent purports to have been issued on September 19, 2023. Sandoz further admits that, on its face, the '714 patent is titled "Methods of Making Bempedoic Acid and Compositions of the Same." Sandoz denies the remaining allegations of Paragraph 32.

33. Esperion is the assignee of, and holds all rights, title and interest in the '714 Patent.

ANSWER:

Paragraph 33 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the online records of the USPTO list Plaintiff as the assignee of the '714 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 33 and on that basis denies these allegations.

34. The '714 Patent currently expires on June 19, 2040.

ANSWER:

Paragraph 34 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the FDA's Orange Book lists June 19, 2040 as the expiration date of the '714 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 34 and on that basis denies these allegations.

35. U.S. Patent No. 11,613,511 (the "'511 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on March 28, 2023. A true and correct copy of the '511 Patent is attached hereto as "Exhibit C."

ANSWER:

Paragraph 35 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Exhibit C of Plaintiff's Complaint purports to be a copy of the '511 patent. Sandoz further admits that the face of the '511 patent states that the '511 patent purports to have been issued on March 28, 2023. Sandoz further admits that, on its face, the '511 patent is titled "Methods of Making Bempedoic Acid and Compositions of the Same." Sandoz denies the remaining allegations of Paragraph 35.

36. Esperion is the assignee of, and holds all rights, title and interest in the '511 Patent.

ANSWER:

Paragraph 36 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the online records of the USPTO list Plaintiff as the assignee of the '511 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 36 and on that basis denies these allegations.

37. The '511 Patent currently expires on June 19, 2040.

ANSWER:

Paragraph 37 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the FDA's Orange Book lists June 19, 2040 as the expiration date of the '511 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 37 and on that basis denies these allegations.

38. U.S. Patent No. 10,912,751 (the "'751 Patent"), entitled "Fixed Dose Combinations and Formulations Comprising ETC1002 and Ezetimibe and Methods of Treating or Reducing the Risk of Cardiovascular Disease," was duly and legally issued on February 9, 2021. A true and correct copy of the '751 Patent is attached hereto as "Exhibit D."

ANSWER:

Paragraph 38 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Exhibit D of Plaintiff's Complaint purports to be a copy of the '751 patent. Sandoz further admits that the face of the '751 patent states that the '751 patent purports to have been issued on February 9, 2021. Sandoz further admits that, on its face, the '751 patent is titled "Fixed Dose Combinations and Formulations Comprising ETC1002 and Ezetimibe and Methods of Treating or Reducing the Risk of Cardiovascular Disease." Sandoz denies the remaining allegations of Paragraph 38.

39. Esperion is the assignee of, and holds all rights, title and interest in the '751 Patent.

ANSWER:

Paragraph 39 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the online records of the USPTO list Plaintiff as the assignee of the '751 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 39 and on that basis denies these allegations.

40. The '751 Patent currently expires on March 14, 2036.

ANSWER:

Paragraph 40 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the FDA's Orange Book lists March 14, 2036 as the expiration date of the '751 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 40 and on that basis denies these allegations.

41. U.S. Patent No. 11,744,816 (the "'816 Patent"), entitled "Fixed Dose Combinations and Formulations Comprising ETC1002 and Ezetimibe and Methods of Treating or Reducing the Risk of Cardiovascular Disease," was duly and legally issued on September 5, 2023. A true and correct copy of the '816 Patent is attached hereto as "Exhibit E."

ANSWER:

Paragraph 41 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Exhibit E of Plaintiff's Complaint purports to be a copy of the '816 patent. Sandoz further admits that the face of the '816 patent states that the '816 patent purports to have been issued on September 5, 2023. Sandoz further admits that, on its face, the '816 patent is titled "Fixed Dose Combinations and Formulations Comprising ETC1002 and Ezetimibe and Methods of Treating or Reducing the Risk of Cardiovascular Disease." Sandoz denies the remaining allegations of Paragraph 41.

42. Esperion is the assignee of, and holds all rights, title and interest in the '816 Patent.

ANSWER:

Paragraph 42 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the online records of the USPTO list Plaintiff as the assignee of the '816 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 42 and on that basis denies these allegations.

43. The '816 Patent currently expires on March 14, 2036.

ANSWER:

Paragraph 43 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the FDA's Orange Book lists March 14, 2036 as the expiration date of the '816 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 43 and on that basis denies these allegations.

44. All claims of the '584, '714, '511, '751, and '816 Patents are valid, enforceable, and not expired.

ANSWER:

Denied.

ESPERION'S NEXLETOL® PRODUCT

45. Esperion is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets life-saving pharmaceutical products, including NEXLETOL® and NEXLIZET®.

ANSWER:

Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 45 and on that basis denies these allegations.

46. Esperion is the holder of New Drug Application ("NDA") No. 211616, which was approved by the FDA on February 21, 2020, for the marketing and sale of bempedoic acid in the United States under the trade name "NEXLETOL®." Esperion sells NEXLETOL® in the United States pursuant to NDA No. 211616.

ANSWER:

Paragraph 46 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the FDA's website lists Esperion Therapeutics Inc. as the holder of New Drug Application ("NDA") No. 211616 and an initial approval date of February 21, 2020. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 46 and on that basis denies these allegations.

47. NEXLETOL® (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated to 1) reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD, and 2) as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

ANSWER:

Sandoz admits that the package insert for NEXLETOL® dated 03/2024, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/211616s012s013lbl.pdf, states the following:

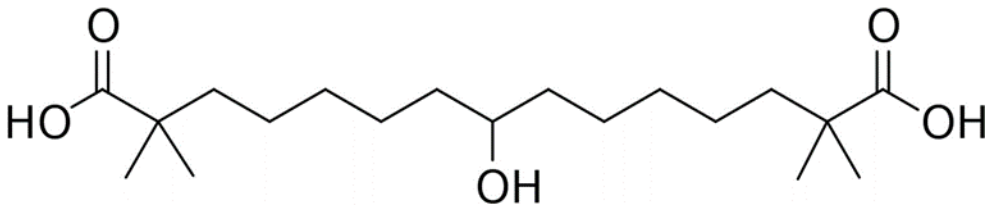
1 INDICATIONS AND USAGE

NEXLETOL is indicated:

- To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with:
  - established cardiovascular disease (CVD), or
  - a high risk for a CVD event but without established CVD.
- As an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

Sandoz denies the remaining allegations of Paragraph 47.

48. Bempedoic acid, the active pharmaceutical ingredient in NEXLETOL®, has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



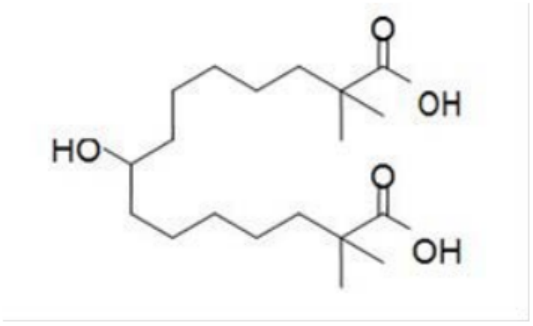
ANSWER:

Sandoz admits that the package insert for NEXLETOL® dated 03/2024, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/211616s012s013lbl.pdf, states the following:

11 DESCRIPTION

NEXLETOL tablets, for oral use, contain bempedoic acid, an adenosine triphosphate-citrate lyase (ACL) inhibitor. The chemical name for bempedoic acid is 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid. The molecular formula is $C_{19}H_{36}O_5$, and the molecular weight is 344.5 grams per mole. Bempedoic acid is a white to off-white crystalline powder that is highly soluble in ethanol, isopropanol and pH 8 phosphate buffer, and insoluble in water and aqueous solutions below pH 5.

Structural formula:



Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 48 and on that basis denies these allegations.

49. The claims of the '584, '714, and '511 Patents cover NEXLETOL®.

ANSWER:

Paragraph 49 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the Orange Book lists the '584, '714, and '511 patents in connection with NDA No. 211616. Sandoz lacks knowledge or information sufficient to form

a belief about the truth of the remaining allegations in Paragraph 49 and on that basis denies these allegations.

50. The '584, '714, and '511 Patents have been listed in connection with NEXLETOL® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."[1]

Footnote 1: The '816 Patent has also been listed in connection with NEXLETOL® in the Orange Book, but Sandoz has not indicated in its NEXLETOL® Notice Letter (defined below) that it has submitted a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '816 Patent.

ANSWER:

Paragraph 50 and any footnotes thereto contain legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the Orange Book lists the '584, '714, '511, and '816 patents in connection with NDA No. 211616 for NEXLETOL®. Sandoz further admits that it sent Sandoz's Mono Notice Letters and that Sandoz's Mono Notice Letters speak for themselves. Footnote 1 is vague and unclear as to which notice letter is referenced and therefore Sandoz denies the allegations contained therein.

ESPERION'S NEXLIZET® PRODUCT

51. Esperion is the holder of NDA No. 211617, which was approved by the FDA on February 26, 2020, for the marketing and sale of a combined bempedoic acid and ezetimibe product in the United States under the trade name "NEXLIZET®." Esperion sells NEXLIZET® in the United States pursuant to NDA No. 211617.

ANSWER:

Paragraph 51 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the FDA's website lists Esperion Therapeutics Inc. as the holder of NDA No. 211617 and an initial approval date of February 26, 2020. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 51 and on that basis denies these allegations.

52. NEXLIZET® is a combination of bempedoic acid, an adenosine triphosphate citrate lyase (ACL) inhibitor, and ezetimibe, a dietary cholesterol absorption inhibitor, indicated as an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH). The bempedoic acid component of NEXLIZET® is indicated to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with (1) established cardiovascular disease (CVD), or (2) a high risk for a CVD event but without established CVD.

ANSWER:

Sandoz admits that the package insert for NEXLIZET® dated 03/2024, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/211617s016s017lbl.pdf, states the following:

1 INDICATIONS AND USAGE

NEXLIZET, a combination of bempedoic acid and ezetimibe, is indicated:

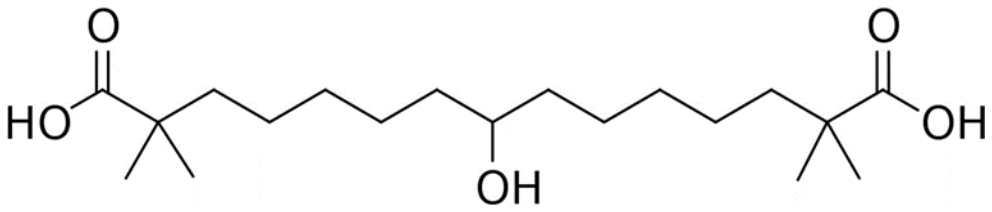
- As an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

The bempedoic acid component of NEXLIZET is indicated:

- To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with:
  - established cardiovascular disease (CVD), or
  - a high risk for a CVD event but without established CVD.

Sandoz denies the remaining allegations of Paragraph 52.

53. Bempedoic acid, one of the active pharmaceutical ingredients in NEXLIZET®, has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



ANSWER:

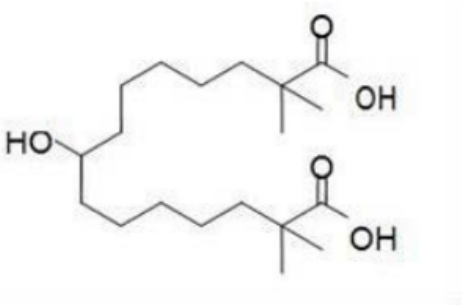
Sandoz admits that the package insert for NEXLIZET® dated 03/2024, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/211617s016s017lbl.pdf, states the following:

11 DESCRIPTION

NEXLIZET tablets, for oral use, contain bempedoic acid, an adenosine triphosphate-citrate lyase (ACL) inhibitor, and ezetimibe, a dietary cholesterol absorption inhibitor.

The chemical name for bempedoic acid is 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid. The molecular formula is $C_{19}H_{36}O_5$, and the molecular weight is 344.5 grams per mole. Bempedoic acid is a white to off-white crystalline powder that is highly soluble in ethanol, isopropanol and pH 8.0 phosphate buffer, and insoluble in water and aqueous solutions below pH 5.

Structural formula:



Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 53 and on that basis denies these allegations.

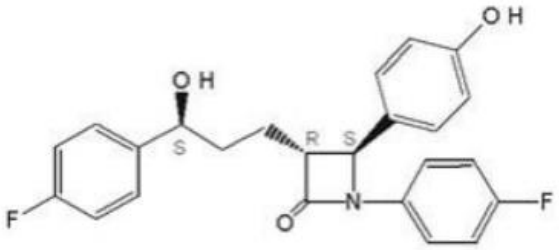
54. Ezetimibe, the other active pharmaceutical ingredient in NEXLIZET®, has the chemical name 1-(4-fluorophenyl)-3(R)-[3-(4-fluorophenyl)-3(S)-hydroxypropyl]-4(S)-(4-hydroxyphenyl)-2-azetidinone.

ANSWER:

Sandoz admits that the package insert for NEXLIZET® dated 03/2024, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/211617s016s017lbl.pdf, states the following:

The chemical name for ezetimibe is 1-(4-fluorophenyl)-3(R)-[3-(4-fluorophenyl)-3(S)-hydroxypropyl]-4(S)-(4-hydroxyphenyl)-2-azetidinone. The molecular formula is $C_{24}H_{21}F_2NO_3$ and the molecular weight is 409.4 grams per mole. Ezetimibe is a white, crystalline powder that is freely to very soluble in ethanol, methanol, and acetone and practically insoluble in water.

Structural formula:



Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 54 and on that basis denies these allegations.

55. The claims of the ’584, ’714, ’511, ’751, and ’816 Patents cover NEXLIZET®.

ANSWER:

Paragraph 55 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the Orange Book lists the ’584, ’714, ’511, ’751, and ’816 patents in connection with NDA No. 211617. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 55 and on that basis denies these allegations.

56. The ’584, ’714, ’511, ’751, and ’816 Patents have been listed in connection with NEXLIZET® in the FDA’s publication, *Approved Drug Products* with Therapeutic Equivalence Evaluations, referred to as the “Orange Book.”

ANSWER:

Paragraph 56 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the Orange Book lists the ’584, ’714, ’511, ’751, and ’816 patents in connection with NDA No. 211617. Sandoz lacks knowledge or information

sufficient to form a belief about the truth of the remaining allegations of Paragraph 56 and on that basis denies these allegations.

SANDOZ'S NEXLETOL® ANDA PRODUCT

57. Upon information and belief, by letter dated April 8, 2024, and received by Esperion via Federal Express no earlier than on April 9, 2024 (the "April 8th NEXLETOL® Notice Letter"), Sandoz notified Esperion that Sandoz had submitted ANDA No. 219347 to the FDA for a generic version of NEXLETOL®.

ANSWER:

Sandoz admits that it sent Plaintiff a notice letter, dated April 8, 2024 ("Sandoz's April 8 Mono Notice Letter"), informing Plaintiff that Sandoz submitted Sandoz's Mono ANDA to FDA seeking approval to market Sandoz's Mono ANDA Product. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 57 and on that basis denies these allegations.

58. Upon information and belief, in the April 8th Notice Letter, Sandoz stated that ANDA No. 219347 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '714 and '511 Patents. Sandoz also contended that the '714 and '511 are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and/or sale of the Sandoz NEXLETOL® ANDA Product.

ANSWER:

Sandoz admits that Sandoz's April 8 Mono Notice Letter informed Plaintiff that Sandoz's Mono ANDA included certifications pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) ("Paragraph IV Certification") for the '714 and '511 patents. Sandoz further admits that Sandoz's April 8 Mono Notice Letter included a detailed statement explaining the '714 and '511 patents are invalid, unenforceable, and/or will not be infringed by Sandoz's Mono Product. Sandoz's April 8 Mono Notice Letter speaks for itself. Sandoz denies the remaining allegations of Paragraph 58.

59. By letter dated April 24, 2024, and received by Esperion via Federal Express no earlier than on April 25, 2024 (the "April 24th NEXLETOL® Notice Letter"), Sandoz notified Esperion that Sandoz had submitted an amended patent certification to ANDA No. 219347.

ANSWER:

Sandoz admits that it sent Plaintiff a notice letter, dated April 24, 2024 ("Sandoz's April 24 Mono Notice Letter") (collectively with Sandoz's April 8 Mono Notice Letter, "Sandoz's Mono Notice Letters"), informing Plaintiff that Sandoz submitted an amended patent certification for Sandoz's Mono ANDA. Sandoz denies the remaining allegations of Paragraph 59.

60. In the April 24th NEXLETOL® Notice Letter, Sandoz stated that it had submitted an amended certification to ANDA No. 219347 to also include a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent. Sandoz also contended that the '584 Patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and/or sale of the Sandoz NEXLETOL® ANDA Product.

ANSWER:

Sandoz admits that Sandoz's April 24 Mono Notice Letter informed Plaintiff that Sandoz's Mono ANDA included a Paragraph IV Certification for the '584 patent. Sandoz further admits that Sandoz's April 24 Mono Notice Letter included a detailed statement explaining the '584 patent is invalid, unenforceable, and/or will not be infringed by Sandoz's Mono Product. Sandoz's April 24 Mono Notice Letter speaks for itself. Sandoz denies the remaining allegations of Paragraph 60.

61. The April 8th and April 24th NEXLETOL® Notice Letters state that Sandoz seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the Sandoz NEXLETOL® ANDA product before the expiration of the '584, '714 and '511 Patents. Upon information and belief, Sandoz intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Sandoz NEXLETOL® ANDA product promptly upon receiving FDA approval to do so.

ANSWER:

Paragraph 61 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Sandoz's Mono Notice Letters informed Plaintiff that Sandoz's Mono ANDA contains Paragraph IV Certifications to obtain approval to engage in the commercial manufacture, use or sale of Sandoz's Mono ANDA Product before the expiration of the '584, '714, and '511 patents. Sandoz's Mono Notice Letters speak for themselves. Sandoz denies the remaining allegations of Paragraph 61.

62. By submitting ANDA No. 219347, Sandoz has represented to the FDA that the Sandoz NEXLETOL® ANDA Product has the same active ingredient, dosage form, and strength as NEXLETOL® and is bioequivalent to NEXLETOL®.

ANSWER:

Paragraph 62 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Sandoz's Mono ANDA contains the required bioavailability and/or bioequivalence data and/or bioequivalence waiver. Sandoz denies the remaining allegations of Paragraph 62.

63. Upon information and belief, Sandoz had knowledge of at least the '714 and '511 Patents when it submitted ANDA No. 219347 to the FDA.

ANSWER:

Paragraph 63 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it was aware of the '714 and '511 patents at the time of filing Sandoz's Mono ANDA.

64. Upon information and belief, Sandoz had knowledge of the '584 Patent at least on or before April 24, 2024.

ANSWER:

Paragraph 64 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it was aware of the '584 patent at the time of sending Sandoz's April 24 Mono Notice Letter.

65. Upon information and belief, Sandoz intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLETOL® ANDA Product immediately and imminently upon approval of ANDA No. 219347.

ANSWER:

Paragraph 65 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted Sandoz's Mono ANDA to FDA seeking approval to market Sandoz's Mono ANDA Product. Sandoz denies the remaining allegations of Paragraph 65.

66. On or before May 10, 2024, pursuant to an Offer of Confidential Access, Sandoz produced portions of its ANDA No. 219347 to Esperion. Sandoz refused to produce the entirety of ANDA No. 219347 to Esperion and refused to provide samples of its ANDA Product or components.

ANSWER:

Sandoz admits it produced portions of Sandoz's Mono ANDA to Plaintiff pursuant to an Offer of Confidential Access under 21 U.S.C. § 355(j)(5)(C)(i)(iii). Sandoz further admits that Plaintiff made unreasonable demands for materials beyond those properly within scope of an Offer of Confidential Access under 21 U.S.C. § 355(j)(5)(C)(i)(iii). Sandoz denies the remaining allegations of Paragraph 66.

67. This action is being commenced before the expiration of forty-five days from the date of Esperion's receipt of the April 8th and April 24th NEXLETOL® Notice Letters.

ANSWER:

Paragraph 67 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Sandoz's April 8 Mono Notice Letter is dated April 8,

2024, Sandoz's April 24 Mono Notice Letter is dated April 24, 2024, and Plaintiff's Complaint was filed on May 23, 2024. Sandoz denies the remaining allegations of Paragraph 67.

SANDOZ'S NEXLIZET® ANDA PRODUCT

68. By letter dated April 24, 2024, and received by Esperion via Federal Express no earlier than on April 25, 2024 (the "NEXLIZET® Notice Letter"), Sandoz notified Esperion that Sandoz had submitted ANDA No. 219346 to the FDA for a generic version of NEXLIZET® (the Sandoz NEXLIZET® ANDA Product").

ANSWER:

Sandoz admits that it sent Plaintiff a notice letter, dated April 24, 2024 ("Sandoz's Combo Notice Letter"), informing Plaintiff that Sandoz submitted Sandoz's Combo ANDA to FDA seeking approval to market Sandoz's Combo ANDA Product. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 68 and on that basis denies these allegations.

69. The NEXLIZET® Notice Letter states that Sandoz seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the Sandoz NEXLIZET® ANDA product before the expiration of the '584, '714, '511, '751, and '816 Patents. Upon information and belief, Sandoz intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Sandoz NEXLIZET® ANDA product promptly upon receiving FDA approval to do so.

ANSWER:

Paragraph 69 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Sandoz's Combo Notice Letter informed Plaintiff that Sandoz's Combo ANDA contains Paragraph IV Certifications to obtain approval to engage in the commercial manufacture, use or sale of Sandoz's Combo ANDA Product before the expiration of the '584, '714, '511, '751, and '816 patents. Sandoz's Combo Notice Letter speaks for itself. Sandoz denies the remaining allegations of Paragraph 69.

70. By submitting ANDA No. 219346, Sandoz has represented to the FDA that the Sandoz NEXLIZET® ANDA Product has the same active ingredient, dosage form, and strength as NEXLIZET® and is bioequivalent to NEXLIZET®.

ANSWER:

Paragraph 70 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits Sandoz's Combo ANDA contains the required bioavailability and/or bioequivalence data and/or bioequivalence waiver. Sandoz denies the remaining allegations of Paragraph 70.

71. In the NEXLIZET® Notice Letter, Sandoz stated that ANDA No. 219346 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584, '714, '511, '751, and '816 Patents. Sandoz also contended that the '584, '714, '511, '751, and '816 Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the Sandoz NEXLIZET® ANDA Product.

ANSWER:

Sandoz admits that Sandoz's Combo Notice Letter informed Plaintiff that Sandoz's Combo ANDA included Paragraph IV Certifications for the '584, '714, '511, '751, and '816 patents. Sandoz further admits that Sandoz's Combo Notice Letter included a detailed statement explaining the '584, '714, '511, '751, and '816 patents are invalid, unenforceable, and/or will not be infringed by Sandoz's Combo Product. Sandoz's Combo Notice Letter speaks for itself. Sandoz denies the remaining allegations of Paragraph 71.

72. Upon information and belief, Sandoz had knowledge of the '714, '511, '751, and '816 Patents when it submitted ANDA No. 219346 to the FDA.

ANSWER:

Paragraph 72 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it was aware of the '714, '511, '751, and '816 patents at the time of filing Sandoz's Combo ANDA.

73. Upon information and belief, Sandoz had knowledge of the '584 Patent at least on or before April 24, 2024.

ANSWER:

Paragraph 73 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it was aware of the '584 patent at the time of sending Sandoz's Combo Notice Letter.

74. Upon information and belief, Sandoz intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product immediately and imminently upon approval of ANDA No. 219346.

ANSWER:

Paragraph 74 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted Sandoz's Combo ANDA to FDA seeking approval to market Sandoz's Combo ANDA Product. Sandoz denies the remaining allegations of Paragraph 74.

75. Sandoz's NEXLIZET® Notice Letter identified invalidity and noninfringement positions with respect to the '584, '714, '511, '751, and '816 Patents and included limited information about the Sandoz NEXLIZET® ANDA Product. Sandoz's Offer of Confidential Access permitted access only to limited, unspecified portions of Sandoz's ANDAs on terms and conditions set by Sandoz.

ANSWER:

Sandoz admits that Sandoz's Combo Notice Letter informed Plaintiff that Sandoz's Combo ANDA contains Paragraph IV Certifications for the '584, '714, '511, '751, and '816 patents and an Offer of Confidential Access consistent with 21 U.S.C. § 355(j)(5)(C)(i)(iii). Sandoz's Combo Notice Letter speaks for itself. Sandoz denies the remaining allegations of Paragraph 75.

76. On April 29, 2024, Esperion requested Sandoz send its proposed Offer of Confidential Access to permit Esperion access to, among other things, the entirety of ANDA No. 219346.

ANSWER:

Denied.

77. Sandoz has not provided Esperion with any portions of its ANDA No. 219346 and refused to provide samples of its ANDA Product or components.

ANSWER:

Sandoz admits it produced portions of Sandoz's Mono ANDA to Plaintiff pursuant to an Offer of Confidential Access under 21 U.S.C. § 355(j)(5)(C)(i)(iii). Sandoz further admits that Plaintiff made unreasonable demands for materials beyond those properly within scope of an Offer of Confidential Access under 21 U.S.C. § 355(j)(5)(C)(i)(iii). Sandoz denies the remaining allegations of Paragraph 77.

78. This action is being commenced before the expiration of forty-five days from the date of Esperion's receipt of the NEXLIZET® Notice Letter.

ANSWER:

Paragraph 78 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Sandoz's Combo Notice Letter is dated April 24, 2024, and Plaintiff's Complaint was filed on May 23, 2024. Sandoz denies the remaining allegations of Paragraph 78.

COUNT I: ALLEGED INFRINGEMENT OF U.S. PATENT NO. 11,926,584 BY SANDOZ'S NEXLETOL® ANDA PRODUCT

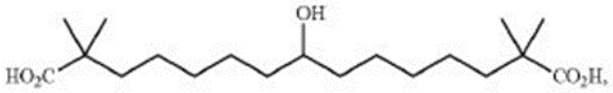
79. Esperion incorporates each of the preceding paragraphs 1 – 78 as if fully set forth herein.

ANSWER:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

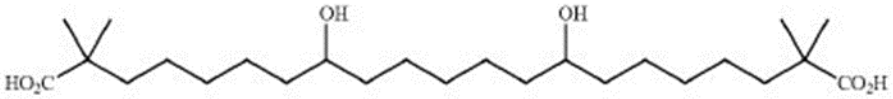
80. Claim 1 of the '584 Patent claims a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):

(V)



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):

(VI)



ANSWER:

Paragraph 80 contains legal conclusions to which no response is required. To the extent a response is required, the claims of '584 patent speak for themselves. Sandoz denies the remaining allegations of Paragraph 80.

81. Sandoz's submission of ANDA No. 219347 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLETOL® ANDA Product before the expiration of the '584 Patent constituted an act of direct and/or indirect infringement of the claims of the '584 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER:

Paragraph 81 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely to address Plaintiff's allegations of infringement of the '584 patent under 35 U.S.C. § 271(e)(2), and expressly reserves the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 81.

82. Sandoz's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLETOL® ANDA Product prior to expiration of the '584 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '584 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b), and/or (c).

ANSWER:

Denied.

83. Upon information and belief, upon FDA approval of Sandoz's ANDA No. 219347, Sandoz will infringe at least claim 1 of the '584 Patent by making, using, offering to sell, and selling the Sandoz NEXLETOL® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '584 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

ANSWER:

Denied.

84. Upon information and belief, Sandoz specifically intends to, and will, actively induce infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(b) when ANDA No. 219347 is approved by marketing the Sandoz NEXLETOL® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '584 Patent, unless enjoined by the Court.

ANSWER:

Denied.

85. Upon information and belief, Sandoz's ANDA No. 219347 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Sandoz NEXLETOL® ANDA Product.

ANSWER:

Sandoz admits that Sandoz's Mono ANDA contains proposed prescribing information.

Sandoz denies the remaining allegations of Paragraph 85.

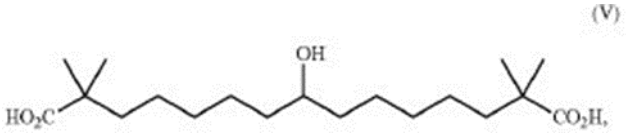
86. Upon information and belief, upon FDA approval of ANDA No. 219347, Sandoz intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Sandoz NEXLETOL® ANDA Product, unless enjoined by the Court, and the Sandoz NEXLETOL® ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

ANSWER:

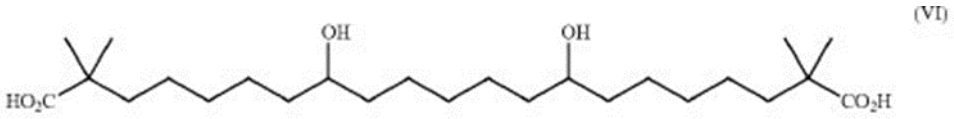
Denied.

87. On information and belief, the proposed package insert will include a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising

administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



ANSWER:

Denied.

88. Upon information and belief, the use of the Sandoz NEXLETOL® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the ’584 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER:

Denied.

89. Upon information and belief, by virtue of its listing in the Orange Book and identification in Sandoz’s April 24th NEXLETOL® Notice Letter, Sandoz has knowledge of the ’584 Patent and knowledge that its Sandoz NEXLETOL® ANDA Product will infringe the ’584 Patent.

ANSWER:

Denied.

90. On information and belief, Sandoz is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Sandoz NEXLETOL® ANDA Product at least according to Sandoz’s proposed package insert and, therefore, will directly infringe at least claim 1 of the ’584 Patent.

ANSWER:

Denied.

91. Upon information and belief, Sandoz intends to, and will, contribute to infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(c) when ANDA No. 219347 is approved, unless enjoined by the Court, because Sandoz knows that the Sandoz NEXLETOL® ANDA Product is especially made or adapted for use in infringing the '584 Patent, and that the Sandoz NEXLETOL® ANDA Product is not suitable for substantial noninfringing use.

ANSWER:

Denied.

92. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '584 Patent.

ANSWER:

Paragraph 92 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely to address Plaintiff's allegations of infringement of the '584 patent under 35 U.S.C. § 271(e)(2), and expressly reserves the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 92.

93. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the Sandoz NEXLETOL® ANDA Product, inducement thereof or contribution thereto, will infringe the '584 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and/or (c).

ANSWER:

Denied.

94. Unless Sandoz is enjoined from directly or indirectly infringing the '584 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER:

Denied.

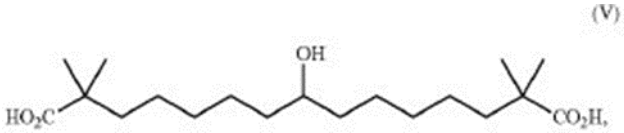
COUNT II: ALLEGED INFRINGEMENT OF U.S. PATENT NO. 11,926,584 BY SANDOZ'S NEXLIZET® ANDA PRODUCT

95. Esperion incorporates each of the preceding paragraphs 1-94 as if fully set forth herein.

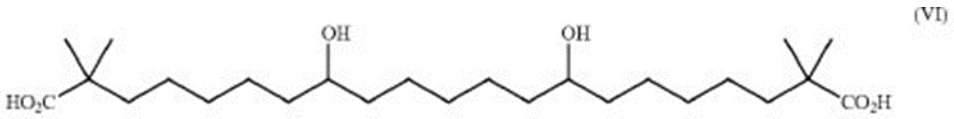
ANSWER:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

96. Claim 1 of the '584 Patent claims a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



ANSWER:

Paragraph 96 contains legal conclusions to which no response is required. To the extent a response is required, the claims of '584 patent speak for themselves. Sandoz denies the remaining allegations of Paragraph 96.

97. Sandoz's submission of ANDA No. 219346 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product before the expiration of the '584 Patent constituted an act of direct and/or indirect infringement of the claims of the '584 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER:

Paragraph 97 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely to address Plaintiff's allegations of infringement of the '584 patent under 35 U.S.C. § 271(e)(2), and expressly reserves the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 97.

98. Sandoz's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product prior to expiration of the '584 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '584 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b), and/or (c).

ANSWER:

Denied.

99. Upon information and belief, upon FDA approval of Sandoz's ANDA No. 219346, Sandoz will infringe at least claim 1 of the '584 Patent by making, using, offering to sell, and selling the Sandoz NEXLIZET ® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '584 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

ANSWER:

Denied.

100. Upon information and belief, Sandoz specifically intends to, and will, actively induce infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(b) when ANDA No. 219346 is approved by marketing the Sandoz NEXLIZET ® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '584 Patent, unless enjoined by the Court.

ANSWER:

Denied.

101. Upon information and belief, Sandoz's ANDA No. 219346 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Sandoz NEXLIZET ® ANDA Product.

ANSWER:

Sandoz admits that Sandoz's Combo ANDA contains proposed prescribing information.

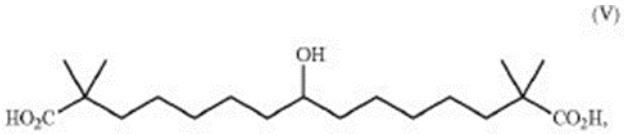
Sandoz denies the remaining allegations of Paragraph 101.

102. Upon information and belief, upon FDA approval of ANDA No. 219346, Sandoz intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET ® ANDA Product, unless enjoined by the Court, and the Sandoz NEXLIZET® ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

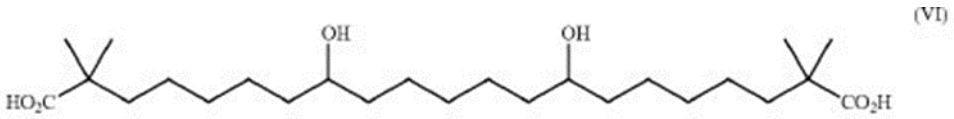
ANSWER:

Denied.

103. On information and belief, the proposed package insert will include a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



ANSWER:

Denied.

104. Upon information and belief, the use of the Sandoz NEXLIZET® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '584 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER:

Denied.

105. Upon information and belief, by virtue of their listing in the Orange Book and identification in Sandoz's NEXLIZET® Notice Letter, Sandoz has knowledge of the '584 Patent and knowledge that its Sandoz NEXLIZET® ANDA Product will infringe the '584 Patent.

ANSWER:

Denied.

106. On information and belief, Sandoz is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Sandoz NEXLIZET® ANDA Product at least according to Sandoz's proposed package insert and, therefore, will directly infringe at least claim 1 of the '584 Patent.

ANSWER:

Denied.

107. Upon information and belief, Sandoz intends to, and will, contribute to infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(c) when ANDA No. 219346 is approved, unless enjoined by the Court, because Sandoz knows that the Sandoz NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '584 Patent, and that the Sandoz NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

ANSWER:

Denied.

108. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '584 Patent.

ANSWER:

Paragraph 108 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely to address Plaintiff's allegations of infringement of the '584 patent under 35 U.S.C. § 271(e)(2), and expressly reserves the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 108.

109. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '584 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and/or (c).

ANSWER:

Denied.

110. Unless Sandoz is enjoined from directly or indirectly infringing the '584 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER:

Denied.

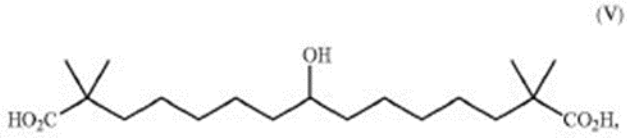
COUNT III: ALLEGED INFRINGEMENT OF U.S. PATENT NO. 11,760,714 BY SANDOZ'S NEXLETOL® ANDA PRODUCT

111. Esperion incorporates each of the preceding paragraphs 1-110 as if fully set forth herein.

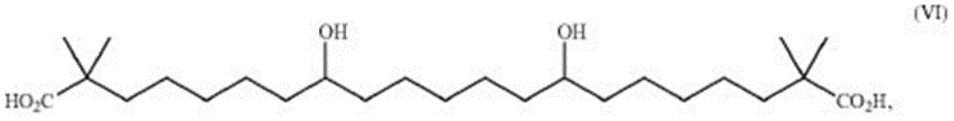
ANSWER:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

112. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and a pharmaceutically acceptable excipient.

ANSWER:

Paragraph 112 contains legal conclusions to which no response is required. To the extent a response is required, the claims of '714 patent speak for themselves. Sandoz denies the remaining allegations of Paragraph 112.

113. Sandoz's submission of ANDA No. 219347 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLETOL® ANDA Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER:

Paragraph 113 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely to address Plaintiff's allegations of infringement of the '714 patent under 35 U.S.C. § 271(e)(2), and expressly reserves the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 113.

114. Sandoz's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLETOL® ANDA Product prior to expiration of the '714 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER:

Denied.

115. Upon information and belief, upon FDA approval of ANDA No. 219347, Sandoz intends to, and will, infringe at least claim 1 of the '714 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Sandoz NEXLETOL® ANDA Product, unless enjoined by the Court.

ANSWER:

Denied.

116. Upon information and belief, by virtue of its listing in the Orange Book and identification in Sandoz's April 8th and April 24th NEXLETOL® Notice Letters, Sandoz has knowledge of the '714 Patent and knowledge that its Sandoz NEXLETOL® ANDA Product will infringe the '714 Patent.

ANSWER:

Denied.

117. Upon information and belief, Sandoz intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No. 219347 is approved by marketing the Sandoz NEXLETOL® ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

ANSWER:

Denied.

118. Upon information and belief, Sandoz intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA No. 219347 is approved, unless enjoined by the Court, because Sandoz knows that the Sandoz NEXLETOL® ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the Sandoz NEXLETOL® ANDA Product is not suitable for substantial noninfringing use.

ANSWER:

Denied.

119. Sandoz's infringement is imminent because, among other things, Sandoz has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLETOL® ANDA Product before the expiration of the '714 Patent.

ANSWER:

Denied.

120. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

ANSWER:

Paragraph 120 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely to address Plaintiff's allegations of infringement of the '714 patent under 35 U.S.C. § 271(e)(2),

and expressly reserves the right to contest subject matter jurisdiction as to other allegations.

Sandoz denies the remaining allegations of Paragraph 120.

121. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the Sandoz NEXLETOL® ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER:

Denied.

122. Unless Sandoz is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER:

Denied.

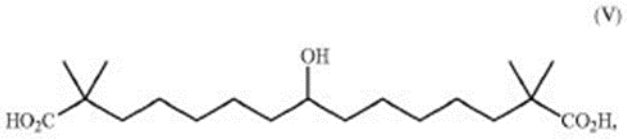
COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 11,760,714 BY SANDOZ'S NEXLIZET® ANDA PRODUCT

123. Esperion incorporates each of the preceding paragraphs 1-122 as if fully set forth herein.

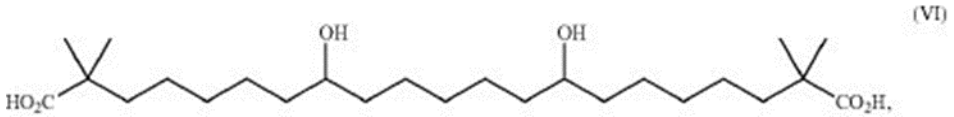
ANSWER:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

124. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and a pharmaceutically acceptable excipient.

ANSWER:

Paragraph 124 contains legal conclusions to which no response is required. To the extent a response is required, the claims of '714 patent speak for themselves. Sandoz denies the remaining allegations of Paragraph 124.

125. Sandoz's submission of ANDA No. 219346 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER:

Paragraph 125 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction to address Plaintiff's allegations of infringement of the '714 patent under 35 U.S.C. § 271(e)(2), and expressly reserves the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 125.

126. Sandoz's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product prior to expiration of the '714 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER:

Denied.

127. Upon information and belief, upon FDA approval of ANDA No. 219346, Sandoz intends to, and will, infringe at least claim 1 of the '714 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, unless enjoined by the Court.

ANSWER:

Denied.

128. Upon information and belief, by virtue of its listing in the Orange Book and identification in Sandoz's NEXLIZET® Notice Letter, Sandoz has knowledge of the '714 Patent and knowledge that its Sandoz NEXLIZET® ANDA Product will infringe the '714 Patent.

ANSWER:

Denied.

129. Upon information and belief, Sandoz intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No. 219346 is approved by marketing the Sandoz NEXLIZET® ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

ANSWER:

Denied.

130. Upon information and belief, Sandoz intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA No. 219346 is approved, unless enjoined by the Court, because Sandoz knows that the Sandoz NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the Sandoz NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

ANSWER:

Denied.

131. Sandoz's infringement is imminent because, among other things, Sandoz has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product before the expiration of the '714 Patent.

ANSWER:

Denied.

132. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

ANSWER:

Paragraph 132 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely to address Plaintiff's allegations of infringement of the '714 patent under 35 U.S.C. § 271(e)(2), and expressly reserves the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 132.

133. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER:

Denied.

134. Unless Sandoz is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER:

Denied.

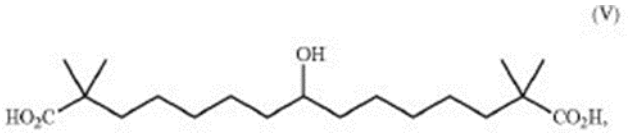
COUNT V: ALLEGED INFRINGEMENT OF U.S. PATENT NO. 11,613,511 BY SANDOZ'S NEXLETOL® ANDA PRODUCT

135. Esperion incorporates each of the preceding paragraphs 1-134 as if fully set forth herein.

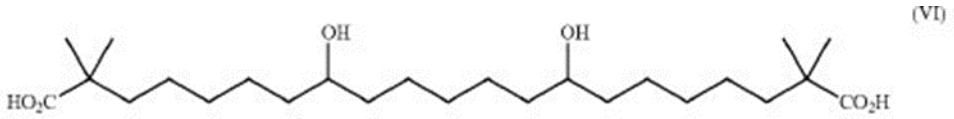
ANSWER:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

136. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles (2θ): 10.3±0.2, 10.4±0.2, 17.9±0.2, 18.8±0.2, 19.5±0.2, and 20.7±0.2.

ANSWER:

Paragraph 136 contains legal conclusions to which no response is required. To the extent a response is required, the claims of '511 patent speak for themselves. Sandoz denies the remaining allegations of Paragraph 136.

137. Sandoz's submission of ANDA No. 219347 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLETOL® ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER:

Paragraph 137 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely to address Plaintiff's allegations of infringement of the '511 patent under 35 U.S.C. § 271(e)(2), and expressly reserves the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 137.

138. Sandoz's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLETOL® ANDA Product prior to expiration of the '511 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the

'511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER:

Denied.

139. Upon information and belief, upon FDA approval of ANDA No. 219347, Sandoz intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Sandoz NEXLETOL® ANDA Product, unless enjoined by the Court.

ANSWER:

Denied.

140. Upon information and belief, by virtue of its listing in the Orange Book and identification in Sandoz's April 8th and April 24th NEXLETOL® Notice Letters, Sandoz has knowledge of the '511 Patent and knowledge that its Sandoz NEXLETOL® ANDA Product will infringe the '511 Patent.

ANSWER:

Denied.

141. Upon information and belief, Sandoz intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA No. 219347 is approved by marketing the Sandoz NEXLETOL® ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

ANSWER:

Denied.

142. Upon information and belief, Sandoz intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c) when ANDA No. 219347 is approved, unless enjoined by the Court, because Sandoz knows that the Sandoz NEXLETOL® ANDA Product is especially made or adapted for use in infringing the '511 Patent, and that the Sandoz NEXLETOL® ANDA Product is not suitable for substantial noninfringing use.

ANSWER:

Denied.

143. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

ANSWER:

Paragraph 143 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely to address Plaintiff's allegations of infringement of the '511 patent under 35 U.S.C. § 271(e)(2), and expressly reserves the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 143.

144. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the Sandoz NEXLETOL® ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER:

Denied.

145. Unless Sandoz is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER:

Denied.

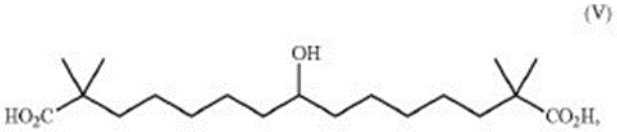
COUNT VI: ALLEGED INFRINGEMENT OF U.S. PATENT NO. 11,613,511 BY SANDOZ'S NEXLIZET® ANDA PRODUCT

146. Esperion incorporates each of the preceding paragraphs 1-145 as if fully set forth herein.

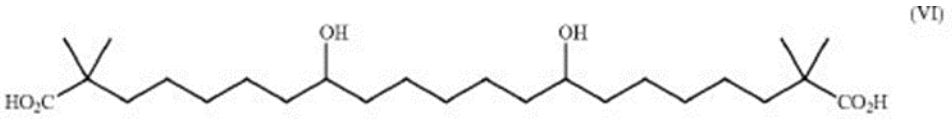
ANSWER:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

147. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles (2θ): 10.3±0.2, 10.4±0.2, 17.9±0.2, 18.8±0.2, 19.5±0.2, and 20.7±0.2.

ANSWER:

Paragraph 147 contains legal conclusions to which no response is required. To the extent a response is required, the claims of '511 patent speak for themselves. Sandoz denies the remaining allegations of Paragraph 147.

148. Sandoz's submission of ANDA No. 219346 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER:

Paragraph 148 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely to address Plaintiff's allegations of infringement of the '511 patent under 35 U.S.C. § 271(e)(2), and expressly reserves the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 148.

149. Sandoz's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product prior to expiration of the '511 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the

'511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER:

Denied.

150. Upon information and belief, upon FDA approval of ANDA No. 219346, Sandoz intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, unless enjoined by the Court.

ANSWER:

Denied.

151. Upon information and belief, by virtue of its listing in the Orange Book and identification in Sandoz's NEXLIZET® Notice Letter, Sandoz has knowledge of the '511 Patent and knowledge that its Sandoz NEXLIZET® ANDA Product will infringe the '511 Patent.

ANSWER:

Denied.

152. Upon information and belief, Sandoz intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA No. 219346 is approved by marketing the Sandoz NEXLIZET® ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

ANSWER:

Denied.

153. Upon information and belief, Sandoz intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c) when ANDA No. 219346 is approved, unless enjoined by the Court, because Sandoz knows that the Sandoz NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '511 Patent, and that the Sandoz NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

ANSWER:

Denied.

154. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

ANSWER:

Paragraph 154 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely to address Plaintiff's allegations of infringement of the '511 patent under 35 U.S.C. § 271(e)(2), and expressly reserves the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 154.

155. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER:

Denied.

156. Unless Sandoz is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER:

Denied.

COUNT VII: ALLEGED INFRINGEMENT OF U.S. PATENT NO. 10,912,751 BY SANDOZ'S NEXLIZET® ANDA PRODUCT

157. Esperion incorporates each of the preceding paragraphs 1-156 as if fully set forth herein.

ANSWER:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

158. Claim 1 of the '751 Patent claims a method of treating familial hypercholesterolemia in a subject in need thereof, the method comprising administering a fixed-dosed combination of 8- hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and Ezetimibe to the subject, wherein the fixed-dose combination comprises a fixed 180 milligram (mg) dose of 8-hydroxy-2,2, 14, 14- tetramethylpentadecanedioic acid and a fixed 10 milligram (mg) dose of Ezetimibe.

ANSWER:

Paragraph 158 contains legal conclusions to which no response is required. To the extent a response is required, the claims of '751 patent speak for themselves. Sandoz denies the remaining allegations of Paragraph 158.

159. Sandoz's submission of ANDA No. 219346 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product before the expiration of the '751 Patent constituted an act of infringement of the claims of the '751 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER:

Paragraph 159 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely to address Plaintiff's allegations of infringement of the '751 patent under 35 U.S.C. § 271(e)(2), and expressly reserves the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 159.

160. Sandoz's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product prior to expiration of the '751 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '751 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b), and/or (c).

ANSWER:

Denied.

161. Upon information and belief, upon FDA approval of Sandoz's ANDA No. 219346, Sandoz will infringe at least claim 1 of the '751 Patent by making, using, offering to sell, and selling the Sandoz NEXLIZET® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '751 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

ANSWER:

Denied.

162. Upon information and belief, Sandoz specifically intends to, and will, actively induce infringement of at least claim 1 of the '751 Patent under 35 U.S.C. § 271(b) when ANDA No. 219346 is approved by marketing the Sandoz NEXLIZET® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '751 Patent, unless enjoined by the Court.

ANSWER:

Denied.

163. Upon information and belief, Sandoz's ANDA No. 219346 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Sandoz NEXLIZET® ANDA Product.

ANSWER:

Sandoz admits that Sandoz's Combo ANDA contains proposed prescribing information.

Sandoz denies the remaining allegations of Paragraph 163.

164. Upon information and belief, upon FDA approval of ANDA No. 219346, Sandoz intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, unless enjoined by the Court, and the Sandoz NEXLIZET® ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

ANSWER:

Denied.

165. Upon information and belief, the proposed package insert will include a method of treating familial hypercholesterolemia in a subject in need thereof, the method comprising administering a fixed-dosed combination of 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and Ezetimibe to the subject, wherein the fixed-dose combination comprises a fixed 180 milligram (mg) dose of 8-hydroxy-2,2, 14, 14-tetramethylpentadecanedioic acid and a fixed 10 milligram (mg) dose of Ezetimibe.

ANSWER:

Denied.

166. Upon information and belief, the use of the Sandoz NEXLIZET® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '751 Patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER:

Denied.

167. Upon information and belief, by virtue of its listing in the Orange Book and identification in Sandoz's NEXLIZET® Notice Letter, Sandoz has knowledge of the '751 Patent and knowledge that its Sandoz NEXLIZET® ANDA Product will infringe the '751 Patent.

ANSWER:

Denied.

168. On information and belief, Sandoz is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Sandoz NEXLIZET® ANDA Product at least according to Sandoz's proposed package insert and, therefore, will directly infringe at least claim 1 of the '751 Patent.

ANSWER:

Denied.

169. Upon information and belief, Sandoz intends to, and will, contribute to infringement of at least claim 1 of the '751 Patent under 35 U.S.C. § 271(c) when ANDA No. 219346 is approved, unless enjoined by the Court, because Sandoz knows that the Sandoz NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '751 Patent, and that the Sandoz NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

ANSWER:

Denied.

170. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '751 Patent.

ANSWER:

Paragraph 170 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely to address Plaintiff's allegations of infringement of the '751 patent under 35 U.S.C. § 271(e)(2), and expressly reserves the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 170.

171. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '751 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER:

Denied.

172. Unless Sandoz is enjoined from directly or indirectly infringing the '751 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER:

Denied.

COUNT VIII: INFRINGEMENT OF U.S. PATENT NO. 11,744,816 BY SANDOZ'S NEXLIZET® ANDA PRODUCT

173. Esperion incorporates each of the preceding paragraphs 1-172 as if fully set forth herein.

ANSWER:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

174. Claim 1 of the '816 Patent claims a method of lowering LDL-C in a subject in need thereof, the method comprising administering 180 mg 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and 10 mg Ezetimibe to the subject, wherein the subject has familial hypercholesterolemia.

ANSWER:

Paragraph 174 contains legal conclusions to which no response is required. To the extent a response is required, the claims of '816 patent speak for themselves. Sandoz denies the remaining allegations of Paragraph 174.

175. Sandoz's submission of ANDA No. 219346 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product before the expiration of the '816 Patent constituted an act of infringement of the claims of the '816 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER:

Paragraph 175 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely to address Plaintiff's allegations of infringement of the '816 patent under 35 U.S.C. § 271(e)(2), and expressly reserves the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 175.

176. Sandoz's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product prior to expiration of the '816 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '816 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b), and/or (c).

ANSWER:

Denied.

177. Upon information and belief, upon FDA approval of Sandoz's ANDA No. 219346, Sandoz will infringe at least claim 1 of the '816 Patent by making, using, offering to sell, and selling the Sandoz NEXLIZET® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '816 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

ANSWER:

Denied.

178. Upon information and belief, Sandoz specifically intends to, and will, actively induce infringement of at least claim 1 of the '816 Patent under 35 U.S.C. § 271(b) when ANDA No. 219346 is approved by marketing the Sandoz NEXLIZET® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '816 Patent, unless enjoined by the Court.

ANSWER:

Denied.

179. Upon information and belief, Sandoz's ANDA No. 219346 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Sandoz NEXLIZET® ANDA Product.

ANSWER:

Sandoz admits that Sandoz's Combo ANDA contains proposed prescribing information.

Sandoz denies the remaining allegations of Paragraph 179.

180. Upon information and belief, upon FDA approval of ANDA No. 219346, Sandoz intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, unless enjoined by the Court, and the Sandoz NEXLIZET® ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

ANSWER:

Denied.

181. Upon information and belief, the proposed package insert will include a method of lowering LDL-C in a subject in need thereof, the method comprising administering 180 mg 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and 10 mg Ezetimibe to the subject, wherein the subject has familial hypercholesterolemia.

ANSWER:

Denied.

182. Upon information and belief, the use of the Sandoz NEXLIZET® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '816 Patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER:

Denied.

183. Upon information and belief, by virtue of its listing in the Orange Book and identification in Sandoz's Nexlizet® Notice Letter, Sandoz has knowledge of the '816 Patent and knowledge that its Sandoz NEXLIZET® ANDA Product will infringe the '816 Patent.

ANSWER:

Denied.

184. Upon information and belief, Sandoz is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Sandoz NEXLIZET® ANDA Product at least according to Sandoz's proposed package insert and, therefore, will directly infringe at least claim 1 of the '816 Patent.

ANSWER:

Denied.

185. Upon information and belief, Sandoz intends to, and will, contribute to infringement of at least claim 1 of the '816 Patent under 35 U.S.C. § 271(c) when ANDA No. 219346 is approved, unless enjoined by the Court, because Sandoz knows that the Sandoz NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '816 Patent, and that the Sandoz NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

ANSWER:

Denied.

186. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '816 Patent.

ANSWER:

Paragraph 186 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely to address Plaintiff's allegations of infringement of the '816 patent under 35 U.S.C. § 271(e)(2), and expressly reserves the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 186.

187. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '816 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER:

Denied.

188. Unless Sandoz is enjoined from directly or indirectly infringing the '816 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER:

Denied.

RESPONSES TO PRAYER FOR RELIEF

All remaining allegations not specifically admitted herein are denied. Sandoz further denies that Plaintiff is entitled to any of the relief set forth in its "Prayer for Relief" or to any relief whatsoever.

DEFENSES

Without any admission or implication as to burden of proof and expressly reserving its right to assert any additional defenses or counterclaims that discovery may reveal, Sandoz asserts the following defenses:

FIRST DEFENSE
(NON-INFRINGEMENT OF THE '584, '714, AND '511 PATENTS BY SANDOZ'S MONO PRODUCT)

The manufacture, use, sale, offer for sale, and/or importation of Sandoz's Mono ANDA Product does not and will not infringe, induce infringement of, and/or contribute to the infringement of any valid and/or enforceable claims of the '584, '714, and '511 patents, either literally or by the doctrine of equivalents. For example, without limitation, the manufacture, use, sale, offer for sale, or importation of Sandoz's Mono ANDA Product has not infringed, does not infringe, and would not infringe any valid claim of the '584, '714, and '511 patents for at least the reasons set forth in Sandoz's Mono Notice Letters.

SECOND DEFENSE
(NON-INFRINGEMENT OF THE '584, '714, '511, '751, AND '816 PATENTS BY SANDOZ'S COMBO PRODUCT)

The manufacture, use, sale, offer for sale, and/or importation of Sandoz's Combo ANDA Product does not and will not infringe, induce infringement of, and/or contribute to the infringement of any valid and/or enforceable claims of the '584, '714, '511, '751, and '816

patents, either literally or by the doctrine of equivalents. For example, without limitation, the manufacture, use, sale, offer for sale, or importation of Sandoz's Combo ANDA Product has not infringed, does not infringe, and would not infringe any valid claim of the '584, '714, '511, '751, and '816 patents for at least the reasons set forth in Sandoz's Combo Notice Letter.

THIRD DEFENSE
(INVALIDITY OF THE '584, '714, '511, '751, AND '816 PATENTS)

One or more claims of the '584, '714, '511, '751, and '816 patents are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including without limitation, one or more of Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents. For example, without limitation, the '584, '714, '511, '751, and '816 patents are invalid for at least the reasons set forth in Sandoz's Mono Notice Letters and Sandoz's Combo Notice Letter.

FOURTH DEFENSE
(FAILURE TO STATE A CLAIM FOR DIRECT INFRINGEMENT)

Plaintiff has failed to state a claim upon which relief can be granted with respect to purported direct infringement of the '584, '714, '511, '751, and '816 patents. The Complaint contains only conclusory allegations including that "Sandoz intends to, and will, infringe at least [a claim] under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing [Sandoz's ANDA Products]." As such, Plaintiff's Complaint fails to state a claim for direct infringement.

FIFTH DEFENSE
(FAILURE TO STATE A CLAIM FOR INDIRECT INFRINGEMENT)

Plaintiff has failed to state a claim upon which relief can be granted with respect to purported indirect infringement of the '584, '714, '511, '751, and '816 patents. The Complaint contains only conclusory allegations including that "Sandoz intends to, and will, actively induce infringement of at least [a claim] under 35 U.S.C. § 271(b) when [Sandoz's ANDAs are] approved" and "Sandoz intends to, and will, contribute to infringement of at least [a claim] under 35 U.S.C. § 271(c) when [Sandoz's ANDAs are] approved." As such, Plaintiff's Complaint fails to state a claim for either induced infringement or contributory infringement.

SIXTH DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION UNDER 35 U.S.C. § 271(a), (b), (c))

The Court lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), and (c) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2022.

SEVENTH DEFENSE
(NOT AN EXCEPTIONAL CASE)

Sandoz's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

EIGHTH DEFENSE
(SAFE HARBOR UNDER 35 U.S.C. § 271(e)(1))

Pursuant to 35 U.S.C. § 271(e)(1), Sandoz's actions do not constitute infringement.

NINTH DEFENSE
(ADDITIONAL DEFENSES DISCOVERY MAY REVEAL)

Any additional defenses that discovery may reveal.

RESERVATION OF DEFENSES

Sandoz hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure, Local Patent Rules, and U.S. Patent Law and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation, including unenforceability.

COUNTERCLAIMS OF SANDOZ INC.

Defendant/Counterclaim-Plaintiff Sandoz Inc. ("Sandoz") brings the following Counterclaims against Plaintiff/Counterclaim-Defendant Esperion Therapeutics, Inc. ("Esperion"), and states as follows:

NATURE OF THE ACTION

1. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C), based on an actual controversy between the parties to declare that Sandoz is free to continue to seek approval of its Abbreviated New Drug Application ("ANDA") Nos. 219347 ("Sandoz's Mono ANDA") and 219346 ("Sandoz's Combo ANDA") (collectively, "Sandoz's ANDAs"), and upon approval by the U.S. Food and Drug Administration ("FDA"), to engage in commercial manufacture, importation, sale, and/or offer for sale of the products described in Sandoz's ANDA Nos. 219347 ("Sandoz's Mono ANDA Product") and 219346 ("Sandoz's Combo ANDA Product") (collectively, "Sandoz's ANDA Products").

THE PARTIES

2. Sandoz is a corporation organized and existing under the laws of Delaware, with a place of business at 100 College Road West, Princeton, New Jersey 08540-6604.

3. Esperion purports to be a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3891 Ranchero Drive, Suite 150 Ann Arbor, Michigan 48108.

4. Esperion purports to be the assignee of U.S. Patent Nos. 11,926,584 ("'584 patent"), 11,760,714 ("'714 patent"), 11,613,511 ("'511 patent"), 10,912,751 ("'751 patent"), and 11,744,816 ("'816 patent").

5. Esperion purports to be the holder of New Drug Application ("NDA") No. 211616 for the marketing and sale of NEXLETOL® (bempedoic acid) tablets.

6. Esperion purports to be the holder of NDA No. 211617 for the marketing and sale of NEXLIZET® (bempedoic acid and ezetimibe) tablets.

JURISDICTION AND VENUE

7. These Counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C).

8. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331, 1337(a) and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under 21 U.S.C. § 355(j)(5)(C).

9. This Court has personal jurisdiction over Esperion because Esperion has availed itself of the rights and privileges and subjected itself to the jurisdiction of this forum by suing Sandoz in this District, and/or because Esperion conducts substantial business in, and has regular systemic contact with, this District.

10. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400 and 21 U.S.C. § 355(j)(5)(C).

BACKGROUND

11. On May 23, 2024, Esperion filed a Complaint for Patent Infringement ("Complaint") in this Court alleging that the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Mono ANDA Product before the expiration of the '584, '714, and '511 patents would constitute infringement of those patents, either literally or under the doctrine of equivalents. Esperion further alleged that Sandoz will actively induce infringement of, and/or contribute to infringement by others of the '584, '714, and '511 patents.

12. Esperion's Complaint further alleged that the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Combo ANDA Product before the expiration of the '584, '714, '511, '751, and '816 patents would constitute infringement of those patents, either literally or under the doctrine of equivalents. Esperion further alleged that Sandoz will actively induce infringement of, and/or contribute to infringement by others of the '584, '714, '511, '751, and '816 patents.

13. By virtue of Esperion's Complaint, an immediate and justiciable controversy exists between Sandoz, on the one hand, and Esperion, on the other, regarding whether Sandoz's Mono ANDA Product infringes any valid and enforceable claim of the '584, '714, and '511 patents and whether Sandoz's Combo ANDA Product infringes any valid and enforceable claim of the '584, '714, '511, '751, and '816 patents.

PATENTS-IN-SUIT

14. The face of the '584 patent indicates it was issued by the U.S. Patent and Trademark Office ("USPTO") on or about March 12, 2024.

15. The face of the '714 patent indicates it was issued by the USPTO on or about September 19, 2023.

16. The face of the ’511 patent indicates it was issued by the USPTO on or about March 28, 2023.

17. The face of the ’751 patent indicates it was issued by the USPTO on or about February 9, 2021.

18. The face of the ’816 patent indicates that it was issued by the USPTO on or about September 5, 2023.

19. Esperion purports and claims to have the right to enforce the ’584, ’714, ’511, ’751, and ’816 patents.

20. On information and belief, Esperion caused the FDA to publish the ’584, ’714, and ’511 patents in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) in connection with NDA No. 211616 for NEXLETOL®.

21. By maintaining the listing of the ’584, ’714, and ’511 patents in the Orange Book for NDA No. 211616 for NEXLETOL®, Esperion has represented that the ’584, ’714, and ’511 patents cover bempedoic acid tablets, and that a claim of patent infringement may reasonably be asserted against any ANDA applicant, including Sandoz, that is not licensed by Esperion and files an ANDA seeking approval to market bempedoic acid tablets before the expiration of the ’584, ’714, and ’511 patents.

22. On information and belief, Esperion caused the FDA to publish the ’584, ’714, ’511, ’751, and ’816 patents in the Orange Book in connection with NDA No. 211617 for NEXLIZET®.

23. By maintaining the listing of the ’584, ’714, ’511, ’751, and ’816 patents in the Orange Book for NDA No. 211617 for NEXLIZET®, Esperion has represented that the ’584,

'714, '511, '751, and '816 patents cover bempedoic acid and ezetimibe tablets, and that a claim of patent infringement may reasonably be asserted against any ANDA applicant, including Sandoz, that is not licensed by Esperion and files an ANDA seeking approval to market bempedoic acid and ezetimibe tablets before the expiration of the '584, '714, '511, '751, and '816 patents.

SANDOZ'S ANDA NO. 219347

24. Sandoz submitted Sandoz's Mono ANDA with FDA seeking approval to engage in the commercial marketing of Sandoz's Mono ANDA Product before the expiration of the '584, '714, and '511 patents.

25. In accordance with the requirements of 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.52(c), Sandoz sent Esperion a notice letter dated April 8, 2024 ("Sandoz's April 8 Mono Notice Letter"), stating that Sandoz's Mono ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification(s)"), alleging that the '714 and '511 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Sandoz's Mono ANDA Product.

26. In accordance with the requirements of 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.52(c), Sandoz sent Esperion a notice letter dated April 24, 2024 ("Sandoz's April 24 Mono Notice Letter") (collectively with Sandoz's April 8 Mono Notice Letter, "Sandoz's Mono Notice Letters"), stating that Sandoz's Mono ANDA included a Paragraph IV Certification alleging that the '584 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Sandoz's Mono ANDA Product.

27. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), each of Sandoz's Mono Notice Letters included an Offer of Confidential Access ("OCA") to Sandoz's Mono ANDA for the holder of NDA No. 211616 and owner of the '584, '714, and '511 patents.

28. Sandoz's OCA to Sandoz's Mono ANDA complied with the requirements of 21 U.S.C. § 355(j)(5)(C)(i)(III), which states in relevant part that the offer shall be for "confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

29. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) of the Federal Drug and Cosmetic Act, Sandoz attached to Sandoz's Mono Notice Letters a detailed statement of the factual and legal bases for Sandoz's Paragraph IV Certifications ("Sandoz's Mono Detailed Statement").

30. Esperion's receipt of Sandoz's April 8 Mono Notice Letter initiated a 45-day statutory period during which Esperion had the opportunity to file an action for patent infringement with respect to Sandoz's Mono ANDA.

31. On April 29, 2024, counsel for Esperion contacted counsel for Sandoz to identify themselves as representing Esperion with respect to both NEXLETOL® and NEXLIZET® and requested a Word version of the proposed OCA.

32. Sandoz's counsel responded on April 30, 2024 with a Word version of the OCA for Sandoz's Mono ANDA. By email dated May 1, 2024, Esperion demanded revisions to Sandoz's OCA that would have removed many of the restrictions placed by the OCA on access

to Sandoz's confidential information. Esperion's letter also demanded Sandoz's confidential documents and things other than a copy of Sandoz's Mono ANDA.

33. On May 7, 2024, Sandoz's counsel wrote back to explain why Esperion's edits to the OCA provided on May 1, 2024 were not acceptable to Sandoz.

34. Following Sandoz's May 7, 2024 explanation, Esperion proposed new redlines to the OCA for Sandoz's Mono ANDA.

35. By email on May 10, 2024, the parties agreed to revisions to Sandoz's OCA for Sandoz's Mono ANDA, and Sandoz then produced portions of Sandoz's Mono ANDA.

36. On May 23, 2024, Esperion filed this infringement action under 35 U.S.C. § 271(e)(2), asserting the '584, '714, and '511 patents against Sandoz.

SANDOZ'S ANDA NO. 219346

37. Sandoz submitted Sandoz's Combo ANDA with FDA seeking approval to engage in the commercial marketing of Sandoz's Combo ANDA Product before the expiration of the '584, '714, '511, '751, and '816 patents.

38. In accordance with the requirements of 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.52(c), Sandoz sent Esperion a notice letter dated April 24, 2024 ("Sandoz's Combo Notice Letter"), stating that Sandoz's Combo ANDA included Paragraph IV Certifications alleging that the '584, '714, '511, '751, and '816 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Sandoz's Combo Product.

39. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), Sandoz's Combo Notice Letter included an OCA to Sandoz's Combo ANDA for the holder of NDA No. 211617 and owner of the '584, '714, '511, '751, and '816 patents.

40. Sandoz's OCA to Sandoz's Combo ANDA complied with the requirements of 21 U.S.C. § 355(j)(5)(C)(i)(III), which states in relevant part that the offer shall be for "confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

41. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) of the Federal Drug and Cosmetic Act, Sandoz attached to Sandoz's Combo Notice Letter a detailed statement of the factual and legal bases for Sandoz's Paragraph IV Certifications ("Sandoz's Combo Detailed Statement") (collectively with Sandoz's Mono Detailed Statement, "Sandoz's Detailed Statements").

42. Esperion's receipt of Sandoz's April 24 Combo Notice Letter initiated a 45-day statutory period during which Esperion had the opportunity to file an action for patent infringement.

43. Following negotiations between April 29 and May 10, 2024, Sandoz and Esperion agreed on terms for the OCA for Sandoz's Mono ANDA. Although Esperion was provided a Word version of Sandoz's Mono OCA, Esperion never requested modifications to expand it to cover Sandoz's Combo ANDA.

44. Nor did Esperion ever request that the parties execute a second OCA for Sandoz's Combo ANDA with the revisions the parties agreed to on May 10, 2024 with respect to Sandoz's Mono ANDA.

45. On May 23, 2024, Esperion filed this infringement action under 35 U.S.C. § 271(e)(2), asserting the ’584, ’714, ’511, ’751, and ’816 patents against Sandoz.

FIRST COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE ’584 PATENT BY SANDOZ’S MONO PRODUCT)

46. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

47. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C). By virtue of Esperion’s allegations of infringement against Sandoz, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Esperion and Sandoz concerning Sandoz’s non-infringement of the ’584 patent.

48. Sandoz seeks a declaration that no valid or enforceable claim of the ’584 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of Sandoz’s Mono Product.

49. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), Sandoz’s Mono Detailed Statement provides factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the ’584 patent.

50. In Sandoz’s Mono Detailed Statement, Sandoz expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in Sandoz’s Mono Detailed Statement.

51. Because Esperion maintains that the commercial manufacture, use, offer for sale, or sale of Sandoz's Mono Product would infringe the '584 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of Sandoz's Mono Product within the United States has not infringed and will not infringe, directly and/or indirectly, the '584 patent.

52. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of Sandoz's Mono Product has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '584 patent.

SECOND COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '584 PATENT BY SANDOZ'S COMBO PRODUCT)

53. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

54. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C). By virtue of Esperion's allegations of infringement against Sandoz, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Esperion and Sandoz concerning Sandoz's non-infringement of the '584 patent.

55. Sandoz seeks a declaration that no valid or enforceable claim of the '584 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of Sandoz's Combo Product.

56. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), Sandoz's Combo Detailed Statement provides factual and legal bases for why Sandoz has not infringed, is not infringing,

and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the ’584 patent.

57. In Sandoz’s Combo Detailed Statement, Sandoz expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in Sandoz’s Combo Detailed Statement.

58. Because Esperion maintains that the commercial manufacture, use, offer for sale, or sale of Sandoz’s Combo Product would infringe the ’584 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of Sandoz’s Combo Product within the United States has not infringed and will not infringe, directly and/or indirectly, the ’584 patent.

59. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of Sandoz’s Combo Product has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the ’584 patent.

THIRD COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE ’584 PATENT)

60. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

61. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C) and seeks a declaration that the claims of the ’584 patent are invalid. By virtue of Esperion’s allegations of infringement against Sandoz, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Esperion and Sandoz concerning the invalidity of the claims of the ’584 patent.

62. Because Esperion maintains and Sandoz denies that the '584 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '584 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

63. Sandoz is entitled to a declaration that the claims of the '584 patent are invalid.

FOURTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '714 PATENT BY SANDOZ'S MONO PRODUCT)

64. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

65. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C). By virtue of Esperion's allegations of infringement against Sandoz, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Esperion and Sandoz concerning Sandoz's non-infringement of the '714 patent.

66. Sandoz seeks a declaration that no valid or enforceable claim of the '714 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of Sandoz's Mono Product.

67. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), Sandoz's Mono Detailed Statement provides factual and legal bases for why Sandoz has not infringed, is not infringing,

and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the ’714 patent.

68. In Sandoz’s Mono Detailed Statement, Sandoz expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in Sandoz’s Mono Detailed Statement.

69. Because Esperion maintains that the commercial manufacture, use, offer for sale, or sale of Sandoz’s Mono Product would infringe the ’714 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of Sandoz’s Mono Product within the United States has not infringed and will not infringe, directly and/or indirectly, the ’714 patent.

70. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale Sandoz’s Mono Product has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the ’714 patent.

FIFTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE ’714 PATENT BY SANDOZ’S COMBO PRODUCT)

71. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

72. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C). By virtue of Esperion’s allegations of infringement against Sandoz, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Esperion and Sandoz concerning Sandoz’s non-infringement of the ’714 patent.

73. Sandoz seeks a declaration that no valid or enforceable claim of the '714 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of Sandoz's Combo Product.

74. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), Sandoz's Combo Detailed Statement provides factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '714 patent.

75. In Sandoz's Combo Detailed Statement, Sandoz expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in Sandoz's Combo Detailed Statement.

76. Because Esperion maintains that the commercial manufacture, use, offer for sale, or sale of Sandoz's Combo Product would infringe the '714 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of Sandoz's Combo Product within the United States has not infringed and will not infringe, directly and/or indirectly, the '714 patent.

77. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of Sandoz's Combo Product has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '714 patent.

SIXTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '714 PATENT)

78. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

79. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C.

§ 355(j)(5)(C) and seeks a declaration that the claims of the '714 patent are invalid. By virtue of Esperion's allegations of infringement against Sandoz, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Esperion and Sandoz concerning the invalidity of the claims of the '714 patent.

80. Because Esperion maintains and Sandoz denies that the '714 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '714 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

81. Sandoz is entitled to a declaration that the claims of the '714 patent are invalid.

SEVENTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '511 PATENT BY SANDOZ'S MONO PRODUCT)

82. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

83. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C). By virtue of Esperion's allegations of infringement against Sandoz, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Esperion and Sandoz concerning Sandoz's non-infringement of the '511 patent.

84. Sandoz seeks a declaration that no valid or enforceable claim of the ’511 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of Sandoz’s Mono Product.

85. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), Sandoz’s Mono Detailed Statement provides factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the ’511 patent.

86. In Sandoz’s Mono Detailed Statement, Sandoz expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in Sandoz’s Mono Detailed Statement.

87. Because Esperion maintains that the commercial manufacture, use, offer for sale, or sale of Sandoz’s Mono Product would infringe the ’511 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of Sandoz’s Mono Product within the United States has not infringed and will not infringe, directly and/or indirectly, the ’511 patent.

88. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of Sandoz’s Mono Product has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the ’511 patent.

EIGHTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE ’511 PATENT BY SANDOZ’S COMBO PRODUCT)

89. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

90. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C). By virtue of Esperion's allegations of infringement against Sandoz, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Esperion and Sandoz concerning Sandoz's non-infringement of the '511 patent.

91. Sandoz seeks a declaration that no valid or enforceable claim of the '511 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of Sandoz's Combo Product.

92. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), Sandoz's Combo Detailed Statement provides factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '511 patent.

93. In Sandoz's Combo Detailed Statement, Sandoz expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in Sandoz's Combo Detailed Statement.

94. Because Esperion maintains that the commercial manufacture, use, offer for sale, or sale of Sandoz's Combo Product would infringe the '511 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of Sandoz's Combo Product within the United States has not infringed and will not infringe, directly and/or indirectly, the '511 patent.

95. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of Sandoz's Combo Product has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '511 patent.

NINTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '511 PATENT)

96. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

97. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C) and seeks a declaration that the claims of the '511 patent are invalid. By virtue of Esperion's allegations of infringement against Sandoz, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Esperion and Sandoz concerning the invalidity of the claims of the '511 patent.

98. Because Esperion maintains and Sandoz denies that the '511 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '511 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

99. Sandoz is entitled to a declaration that the claims of the '511 patent are invalid.

TENTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '751 PATENT BY SANDOZ'S COMBO PRODUCT)

100. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

101. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C). By virtue of Esperion's allegations of infringement against Sandoz, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Esperion and Sandoz concerning Sandoz's non-infringement of the '751 patent.

102. Sandoz seeks a declaration that no valid or enforceable claim of the '751 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of Sandoz's Combo Product.

103. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), Sandoz's Combo Detailed Statement provides factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '751 patent.

104. In Sandoz's Combo Detailed Statement, Sandoz expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in Sandoz's Combo Detailed Statement.

105. Because Esperion maintains that the commercial manufacture, use, offer for sale, or sale of Sandoz's Combo Product would infringe the '751 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture,

use, importation, offer for sale, or sale of Sandoz's Combo Product within the United States has not infringed and will not infringe, directly and/or indirectly, the '751 patent.

106. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of Sandoz's Combo Product has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '751 patent.

ELEVENTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '751 PATENT)

107. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

108. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C) and seeks a declaration that the claims of the '751 patent are invalid. By virtue of Esperion's allegations of infringement against Sandoz, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Esperion and Sandoz concerning the invalidity of the claims of the '751 patent.

109. Because Esperion maintains and Sandoz denies that the '751 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '751 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

110. Sandoz is entitled to a declaration that the claims of the '751 patent are invalid.

TWELFTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '816 PATENT BY SANDOZ'S COMBO PRODUCT)

111. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

112. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C). By virtue of Esperion's allegations of infringement against Sandoz, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Esperion and Sandoz concerning Sandoz's non-infringement of the '816 patent.

113. Sandoz seeks a declaration that no valid or enforceable claim of the '816 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of Sandoz's Combo Product.

114. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), Sandoz's Combo Detailed Statement provides factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '816 patent.

115. In Sandoz's Combo Detailed Statement, Sandoz expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in Sandoz's Combo Detailed Statement.

116. Because Esperion maintains that the commercial manufacture, use, offer for sale, or sale of Sandoz's Combo Product would infringe the '816 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture,

use, importation, offer for sale, or sale of Sandoz's Combo Product within the United States has not infringed and will not infringe, directly and/or indirectly, the '816 patent.

117. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of Sandoz's Combo Product has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '816 patent.

THIRTEENTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '816 PATENT)

118. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

119. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C) and seeks a declaration that the claims of the '816 patent are invalid. By virtue of Esperion's allegations of infringement against Sandoz, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Esperion and Sandoz concerning the invalidity of the claims of the '816 patent.

120. Because Esperion maintains and Sandoz denies that the '816 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '816 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

121. Sandoz is entitled to a declaration that the claims of the '816 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Defendant/Counterclaim-Plaintiff Sandoz respectfully requests that this Court enter a Judgment and Order:

A. dismissing the Complaint, and the claims for relief contained therein, with prejudice;

B. declaring that Sandoz and Sandoz's Mono Product have not infringed, are not infringing, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '584, '714, and '511 patents;

C. declaring that Sandoz and Sandoz's Combo Product have not infringed, are not infringing, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '584, '714, '511, '751, and '816 patents;

D. declaring that Sandoz and Sandoz's Mono and Combo Products have not infringed, are not infringing, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '584 patent;

E. declaring that the claims of the '584 patent are invalid;

F. declaring that Sandoz and Sandoz's Mono and Combo Products have not infringed, are not infringing, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '714 patent;

G. declaring that the claims of the '714 patent are invalid;

H. declaring that Sandoz and Sandoz's Mono and Combo Products have not infringed, are not infringing, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '511 patent;

I. declaring that the claims of the '511 patent are invalid;

J. declaring that Sandoz and Sandoz's Combo Product have not infringed, are not infringing, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '751 patent;

K. declaring that the claims of the '751 patent are invalid;

L. declaring that Sandoz and Sandoz's Combo Product have not infringed, are not infringing, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '816 patent;

M. declaring that the claims of the '816 patent are invalid;

N. declaring this an exceptional case under 35 U.S.C. § 285 and awarding Sandoz attorney fees, costs, and expenses; and

O. granting Sandoz such other and further relief as this Court deems just and proper.

Dated: July 24, 2024

Respectfully submitted,

/s/ Eric I. Abraham

Eric I. Abraham
HILL WALLACK LLP
21 Roszel Road
Princeton, NJ 08540
T: (609) 924-0808
F: (609) 452-1888
eabraham@hillwallack.com

Mark H. Remus (mremus@crowell.com)
Laura A. Lydigsen (llydigsen@crowell.com)
Mary E. LaFleur (mlafleur@crowell.com)
Eric Moss (emoss@crowell.com)
CROWELL & MORING LLP
455 North Cityfront Plaza Drive
NBC Tower, Suite 3600
Chicago, IL 60611
T: (312) 321-4200
F: (312) 321-4299

Attorneys for Defendant Sandoz Inc.

CERTIFICATE OF SERVICE

I hereby certify that on July 24, 2024, I caused a true and correct copy of the foregoing document to be served via electronic mail on counsel of record in this matter.

Dated: July 24, 2024

Respectfully submitted,

By: */s/ Eric I. Abraham*
Eric I. Abraham